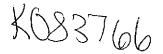
## 13. Summary of Safety and Effectiveness



MAR - 2 2009

#### Submitter 1 4 1

Name of company: S&C Polymer Silicon- und Composite Spezialitaeten GmbH

Address: Robert-Bosch-Strasse 5, D-25335 Elmshorn (Germany)

Phone: 0049 4121 483 0

Fax: 0049 4121 483 184

Contact Person: Dr. Christian Boettcher

Date of preparation: December 2008

#### **Device Name:**

Trade name: PhoGlass Cem

Common Name: PhoGlass Cem

Classification Name: Cement Dental, per 21CFR § 872.3275

### Devices for which Substantial Equivalence is Claimed:

Fuji I (GC Corporation)

#### **Device description:**

PhoGlass Cem is a dental glass ionomer cement intended to be used as an cement for cementing of crowns and bridges, inlays and onlays (metal and ceramic fused to metal), stainless steel crowns, orthodontic bands and used as a base or a liner.

#### Intended Use of the Device:

The device is designed for cementing-applications for dental purposes.

#### Substantial Equivalence:

PhoGlass is substantially equivalent to other legally marketed devices in the United States. The products marketed by S&C Polymer Silicon- und Compositen Spezialitaeten GmbH function in a manner similar to and is intended for the same use as the product marketed by GC.





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Dr. Christian Boettcher Regulatory Compliance Officer S&C Polymer GmbH Robert-Bosch-Strasse 5 D-25335 Elmshorn GERMANY

MAR - 2 2009

Re: K083766

Trade/Device Name: PhoGlass Cem Regulation Number: 21 CFR 872.3275(b)

Regulation Name: Dental Cement

Regulatory Class: II

Product Codes: EMA and EJK Dated: December 17, 2008 Received: December 22, 2008

#### Dear Dr. Boettcher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>.

Sincerely yours,

Ginette Y. Michaud, M.D.

**Acting Director** 

Division of Anesthesiology, General Hospital, Infection Control and Dental Devices Office of Device Evaluation

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Center for Devices and Radiological Health

# 11. Statement of Indication for Use

510(k) Number (if known): 469 3766	
Device Name:	PhoGlass Cem
Indications for Use:	
PhoGlass Cem:  PhoGlass Cem is intended to be used as an insoluble cement for cementing of crowns and bridges, inlays and onlays (metal and ceramic fused to metal), stainless steel crowns, orthodontic bands and used as a base or a liner.	
\	·
Concurrence of CDRH, Office of Device Evaluation (ODE)	
Ovision Sign-Off)  Owision of Anesthesiology, General Hospital  Infection Control, Dental Devices	

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19(k) Number: <u>KOS3766</u>

Over-The-Counter Use